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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,986	01/21/2004	Maria Amparo Lago	P51103C1	4290

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GLAXOSMITHKLINE
Corporate Intellectual Property
UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939

EXAMINER

SACKEY, EBENEZER O

ART UNIT PAPER NUMBER

1626

DATE MAILED: 01/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/761,986	Applicant(s) LAGO ET AL.	
	Examiner EBENEZER SACKY	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 7-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 14 is/are rejected.
- 7) ☒ Claim(s) 5 and 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/21/04 & 08/08/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 1-14 are pending.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed 01/21/04 and 08/08/05 respectively is acknowledged and has been entered into the file. Signed copies of the 1449 are attached herewith.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6 and 14 are, drawn to compounds of structural formula (I), (II) and (III), classified in class 558, subclass 388+.
- II. Claims 7-13 are, drawn to methods of using compounds of formula (I) in treating various disease state, classified in class 514, subclass 475+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process as claimed can be practiced with another materially different product such as shown in WO 95/11211 which refer to calcilytics as compounds able to inhibit calcium receptor activity.

Advisory of Rejoinder

The following is a recitation of M.P.E.P. §821.04, Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02© and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims, which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either (1) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2), or (2) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2), even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26 states that "[m]oney paid by actual mistake or in excess will be refunded, but a mere change of purpose after the payment of money...will not entitle a party to demand such a return..." The fees paid under 37 CFR 1.129(b) were not paid by actual mistake nor paid in excess, therefore, applicant would not be entitled to a refund.

In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

Therefore, in accordance with M.P.E.P. §821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product

Art Unit: 1626

claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Soma G. Simon on 01/10/06 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-6 and 14. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-13 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1626

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements is an additional bond or a hydrogen atom to the nitrogen atom in each of formulae (I), (II) and (III). The said bond or hydrogen atom would complete the valence required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1-4 and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5 and 6 of U.S. Patent No. 6,395,919. Although the conflicting claims are not identical, they are not patentably distinct from each other because there are considerable overlap between the instant claims and the claims of '919'. The instant claims are drawn to specific compounds and species, which overlap with the claims of '919'. See species of claims 5 and 6.

Art Unit: 1626

The instantly claimed compounds differ from the '919' patent in that they are close structural homologs of the instant compounds, for example in formula (II) of '919' wherein A and B are a bond and R₅ is aryl, or a fused aryl, dihydro or tetrahydro fused aryl; X₁ to X₅ are hydrogen, halogen which corresponds to formulae (I), (II) and (III) of the instant claims wherein A is aryl, fused aryl, dihydro or tetrahydro fused aryl.

The instantly claimed compounds differ from '919' in that they are close structural homologs of compounds of formula (I), (II) and (III) as disclosed above.

One of ordinary skill in the art would be motivated to prepare compounds so closely related to the homologous compounds of '919' reference so as to be structurally obvious therefrom, or would be rendered obvious by the teachings of the reference in the absence of any unobvious properties especially since one of ordinary skill would expect compounds so closely related structurally to have the same or virtually the same properties.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Bhatnager et al., (WO 99/51569).

Applicants claim compounds of structural formulae (I), (II) and (III) in which the substituents are as defined in claim 1.

Art Unit: 1626

Bhatnager et al., discloses for example (R)-N-[2-hydroxy-3-(2-cyano-3-(-carbethoxypropyl) phenoxy)propyl]-1,1-dimethyl-2-(2-naphthyl)ethylamine compound, which anticipates the instant invention. See for example page 8, the third species listed, page 30, line 9. The whole reference is replete with anticipatory compounds. See page 30, line 9 i.e., Methyl-4-(oxiranylmethoxy) phenylbenzoyl benzoic ester.

Claim Rejections - 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Del Mar et al., (U.S. Patent Number 6,022,894) or Bhatnagar et al., (WO 99/51569). Applicants claim compounds of structural formulae (I), (II) and (III) wherein substituents A and X₁ to X₅ are as defined in the claims. Applicants further claim the use of the said compounds in treating osteoporosis.

Determination of the scope and content of the prior art (MPEP §2141.01)

Del Mar et al., teach compounds, which generically embraces the instantly claimed compounds. The said compounds of Del Mar et al., have utility against bone diseases such as osteoporosis. See the entire reference, especially column 2, lines 35-64 and column 7, lines 45-67, column 8, lines 1-68 wherein R₁ is substituted aryl; Z is O; each of Y₁, Y₂ and Y₃ is alkylene, R₆ is H; R₂ is OH; each of R₃ and R₄ is lower alkyl and R₅ is aryl. See the preferred embodiments as disclosed in column 10, lines 2-12 where it is disclosed that the preferred aryl (R₁) is phenyl which is optionally substituted, the preferred R₅ is an unsubstituted aryl and examples 7, 14, 23, 30 etc. Additionally, the reference further teaches the use of the compounds in treating various diseases such as abnormal bone or mineral homeostasis and more specifically osteoporosis. See column 3, lines 53-61 and column 4, lines 1-17.

Bhatnagar et al., (569) teach compounds, which generically embraces the instantly claimed compounds, which are used for treating diseases such as osteoporosis. See for example page 4, formula (II) wherein Y₃ is O; Y₁ is alkylene; Y₂ is methylene; R₃ and R₄ are each methyl or ethyl; R₅ is aryl, fused aryl, dihydro or tetrahydro fused aryl; R₇ is OH, R₈ is hydrogen; G is a bond; A and B are, independently a bond or CH₂; and X₁ to X₅ are as defined or example 38a.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Art Unit: 1626

The instantly claimed compounds differ from '894' and '569' in that they are close structural homologs of compounds of formulae (I), (II) and (III) as disclosed above.

Finding of prima facie obviousness---rational and motivation (MPEP §2142-2143)

One of ordinary skill in the art would be motivated to prepare compounds so closely related to be homologous, isomeric or structural analogs of compounds of the reference so as to be structurally obvious therefrom, or would be rendered obvious by the teachings of the references in the absence of any unobvious properties especially since one of ordinary skill in the art would expect compounds so closely related structurally to have similar properties. Furthermore, the skilled artisan would be motivated to use the teachings of the references to prepare compounds in the expectation that all compounds under the genus would be useful for the reference utility i.e., for example treating osteoporosis.

Thus, the instantly claimed compounds would have been suggested to one of ordinary skill absent a showing of unexpected results or properties.

Claims 5-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (571) 272-0704. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272-0699. The fax phone

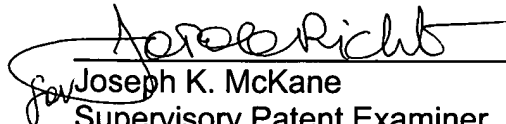
Art Unit: 1626

number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

EOS

January 12, 2006



for Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1600
Technology Center 1